

REMARKS

In the aforesaid Office Action, claims 1-4 and 11-14 were rejected under 35 USC §102(b) as being anticipated by Bazell et al. (U.S. Patent No. 3,884,242), and claim 10 was rejected under 35 USC §102(b) as being anticipated by Inoue (U.S. Patent No. 5,100,386), and claims 6-9 were rejected under 35 USC §103(a) as being unpatentable over Bazell et al. alone. Claims 1-4 and 6-15 are pending (new claim 15 is being added by this amendment).

The Examiner rejected claims 1-4 and 11-14 under 35 USC §102(b) as being anticipated by Bazell et al., and claims 6-9 under 35 USC §103(a) as being unpatentable over Bazell et al. alone, stating that Bazell et al. discloses a catheter with a balloon 16 having a distal shaft section adhesively secured to the catheter shaft (see column 7, lines 42-50 and column 10, lines 41-44), and a tip member 19 having a proximal end adhesively secured to the balloon distal shaft section (see column 8, lines 50-61) and to the catheter shaft (see column 7, lines 64-67).

However, Bazell et al. does not disclose or suggest a catheter with a balloon distal shaft section which is adhesively secured to the catheter shaft and which has an outer surface tapering distally, and with a distal tip member which is adhesively secured to the catheter shaft and the balloon distal shaft section and which has an outer surface tapering distally from the proximal end of the distal tip member toward the distal end thereof, as required by Applicant's claim 1. Specifically, Bazell et al. discloses that the distal tip 19 proximal flange portion 20 may taper inwardly from the shoulder 22 to the proximal edge 22 (i.e., tapering proximally, as most clearly illustrated in Fig. 1; see column 8, lines 6-10, and lines 38-43), and Bazell et al. does not disclose or suggest that the distal tip 19 proximal flange portion 20 may taper distally. Therefore, although Bazell et al. does disclose that the distal tip 19 distal portion 23 tapers distally (see column 8, lines 10-12, and Fig. 4), Bazell et al. does not disclose that the distal tip 19 tapers distally from the

proximal end thereof toward the distal end thereof. Similarly, although Fig. 12 illustrates an embodiment of distal tip 19 which tapers distally from the distal end of the bevel 71, the proximal end of the distal tip 19 of Fig. 12 is butt-joined to the catheter shaft 2 and is therefore not adhesively secured to the balloon distal shaft section as required by Applicant's claim 1.

Moreover, Bazell et al. does not disclose or suggest a balloon distal shaft section which is adhesively secured to the catheter shaft and which has a distally tapering outer surface. Although Bazell et al. discloses an embodiment at column 13, lines 13-35 and illustrated in Fig. 10, in which the balloon (i.e., "outer cuff member 16") is molded or cured to have distal thickened margin portion 60 tapering distally, the portion 60 replaces and has the properties of securing ring 14. Bazell et al. does not disclose or suggest that portion 60 or securing ring 14 is adhesively secured to the shaft. Rather, Bazell et al. explicitly discloses that the securing ring 14 is frictionally fit onto the catheter shaft 2 (see column 7, lines 32-35; and column 10, lines 15-27; disclosing that the frictional securing means/sealing rings 14, 15 mechanically grip onto the catheter shaft 2). Applicant notes that column 7, lines 42-50 of Bazell et al., referenced by the Examiner, discloses that the balloon 16 is adhesively secured to the frictional sealing rings 14, 15. Therefore, in contrast to the Examiner's assertion, it does not disclose that the balloon 16 is adhesively secured to the catheter shaft 2 (or that the frictional sealing rings 14, 15 are adhesively secured to the catheter shaft 2). Therefore, the distally tapering portion 60, which replaces and which thus must have the properties of securing ring 14, is frictionally fit onto the catheter shaft 2 and is not adhesively secured thereto as required by Applicant's claims. In none of the embodiments of Bazell et al. is the balloon distal shaft section adhesively secured to the catheter shaft and tapered distally.

As discussed in Applicant's specification at page 4, lines 3-5, page 7, lines 11-14, and illustrated in the Figures, an embodiment of Applicant's balloon catheter has a balloon distal shaft section and distal tip member which are both adhesively bonded together and to the catheter shaft and which nonetheless both have distally tapering outer

surfaces, providing a distal tip having improved performance as discussed on page 3 of Applicant's specification.

The Examiner rejected claim 10 under 35 USC §102(b) as being anticipated by Inoue. However, Inoue does not disclose or suggest a catheter with a balloon distal shaft section which is adhesively secured to the catheter shaft and which has an outer surface tapering distally, and with a distal tip member which is adhesively secured to the catheter shaft and the balloon distal shaft section and which has an outer surface tapering distally from the proximal end of the distal tip member toward the distal end thereof, as required by Applicant's claim 1. Moreover, the Examiner states that Inoue at column 3, lines 20-25 discloses the proximal end of the tip member adhesively joined to the balloon distal shaft section. However, Applicant has reviewed Inoue and can find no teaching or suggestion of adhesively joining the tip member to the balloon distal shaft section. Inoue appears to disclose that distal tip ring 24 is adhesively joined to the catheter shaft 14, but that fastener 30 is used to secure the balloon 16 to the distal tip ring 24.

Applicant has added new claim 15, requiring that the distally tapering outer surfaces of the balloon distal shaft section and the distal tip member are aligned and taper at the same angle. Support for new claim 15 can be found in Fig. 2.

Attached hereto is a marked-up version of the changes made to the claims by the current Amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

In light of the above amendments and remarks, applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE
IN THE CLAIMS

New claim 15 is added.

Claims 1, 4, 7, 9 and 13 are amended as follows:

1. (Twice Amended) A balloon catheter having a distal end, the balloon catheter comprising:

an elongated catheter shaft having a proximal end, a distal end, a proximal shaft section, a distal shaft section, an inflation lumen, and a guidewire receiving lumen extending along at least a portion thereof [to], the guidewire receiving lumen being in communication with a port at the catheter [shaft] distal end[, and an inflation lumen];

a balloon on the catheter distal [catheter] shaft section [and], having an [inflatable] interior in fluid communication with the inflation lumen, proximal and distal ends, a proximal [balloon] shaft section [adjacent the balloon proximal end], and a distal [balloon] shaft section [adjacent the balloon distal end and being] adhesively secured to the catheter shaft, the balloon distal shaft section having an outer surface tapering distally; and

a distal tip member [on the distal end of the catheter] having proximal and distal ends, an outer surface tapering distally from the proximal end of the distal tip member toward the distal end of the distal tip member, [and being] a lumen in fluid communication with the catheter shaft guidewire receiving lumen, [the proximal end] and a proximal portion adhesively secured to the balloon distal shaft section and the catheter shaft.

4. (Amended) The catheter of Claim 3 wherein the tip member proximal end[s] extends proximally over the distal end of the catheter shaft.

7. (Amended) The catheter of Claim 6 wherein the distal end of the catheter shaft extends distally beyond the balloon distal end in a range from about [1.0] 0.5 to about [5.0] 0.75 millimeters.

9. (Amended) The catheter of Claim 8 wherein the proximal end of the tip member extends distally over the catheter shaft in a range from about [0.1] 0.25 to about 0.5 millimeters.

13. (Amended) A method of forming a [distal tip portion of a] balloon catheter, comprising:

providing a catheter assembly including a catheter shaft having proximal and distal ends, and a balloon having proximal and distal ends with an [inflatable] interior and a distal shaft section with an interior surface;

providing a tip member having proximal and distal ends;

positioning the distal end of the catheter shaft within the interior of the balloon distal shaft section and terminating at a point distal to the balloon distal end;

providing adhesive along the exterior surface of the catheter shaft extending underneath the balloon distal shaft;

positioning the proximal end of the tip member adjacent the balloon distal end;

adhesively bonding at least a portion of the balloon distal shaft section to the catheter shaft; and

adhesively bonding at least a portion of the balloon distal shaft section to the tip member[; and

forming the] , to thereby form a distal tip portion of the catheter having an outer surface tapering distally along the adhesively bonded portion of the balloon distal shaft section and the distal tip member.